UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: LEVAQUIN PRODUCTS LIABILITY LITIGATION,	MDL No. 08-1943 (JRT)
This Document Relates to:	
JOHN SCHEDIN, Plaintiff, v. JOHNSON & JOHNSON; ORTHO-MCNEIL PHARMACEUTICAL, INC.; JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, LLC; and ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; Defendants.	Civil No. 08-5743 (JRT) **ORDER DENYING DEFENDANTS' MOTION IN LIMINE REGARDING POST-2005 LABELING**

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The issue before the Court is whether evidence of Food and Drug Administration ("FDA") labeling of Levaquin, approved after Mr. Schedin was prescribed the drug in 2005, is admissible in this litigation. The evidence is relevant since this case centers on what warnings defendants should have given about Levaquin, and the post-2005 label – based on the experiences with Levaquin from 1997 on – is therefore relevant. For the reasons stated below, the Court finds such evidence not barred by Rule 407, not unduly prejudicial under Rule 403, and not pre-empted. The evidence is thus admissible with an appropriate limiting instruction to the jury.

I. RULE 407

Federal Rule of Evidence 407 bars the admissibility of subsequent remedial measures on the theory "that modifications [that benefit the public] would not be made in the absence of the rule . . . ." *DeLuryea v. Winthrop Labs.*, 697 F.2d 222, 228 (8th Cir. 1983). "An exception to Rule 407 is recognized for evidence of remedial action mandated by superior governmental authority . . . because the policy goal of encouraging remediation would not necessarily be furthered by exclusion of such evidence." *O'Dell v. Hercules, Inc.*, 904 F.2d 1194, 1204 (8th Cir. 1990). Here, the label changes after 2005, including the black box warning, were mandated by the FDA. Since Rule 407 does not bar evidence of subsequent remedial measures that are mandated by a governmental agency, Rule 407 is not applicable in this case. *Underwriters at Lloyd's London v. OSCA, Inc.*, Nos. 03-20398, 03-20817, 03-21021, 2006 WL 941794, at *6 (5th Cir. Apr. 12, 2006); *see also Kociemba v. G.D. Searle & Co.*, 683 F. Supp. 1579, 1581 (D. Minn.

1988) (describing cases where subsequent measures were admissible and ruling that a subsequent FDA label was admissible in a product liability case).

II. PREJUDICE

A further question raised by the admission of the subsequent labeling of Levaquin is whether such evidence is unfairly prejudicial under Rule 403 to defendants since the change in labeling may lead the jury to infer from the FDA's decision – that the labeling was inadequate at some time **after** Mr. Schedin's injury – that it was de facto inadequate **at the time** of the prescription.[1] *See Bartlett v. Mutual Pharm. Co., Inc.*, No. 08-cv-358, 2010 WL 3092649, at *3 (D. N.H. Aug. 2, 2010) ("But the danger is that [later label changes] could be valued too highly by the jury, i.e., viewed as an implicit admission of inadequacy by the manufacturer."). This potential for jury confusion as to the import of label changes and the timeline of those changes naturally conflicts with the defendants' introduction of the FDA's approval of the label at the time of Mr. Schedin's injury as evidence that the warning was contemporaneously adequate.

> Given that [the defendant] intends to use the FDA's approval of [the label] as evidence of the label's adequacy (which is an element of [the] defense), this court does not consider it unfairly prejudicial for [the plaintiff] to counter with evidence that the FDA changed that label less than two years later, especially to the extent that the FDA relied on information available to [the defendant] at the time of [the plaintiff's] prescription. One might even argue that it would be unfairly prejudicial to **prevent** Bartlett from responding in kind.

Bartlett, 2010 WL 3092649, at *3 (internal citations omitted; emphasis original).

[1] There is no evidence in the record thus far that the FDA's decision to require a black box warning was based solely on new evidence which came after 2005, a factor which could affect the relevancy of evidence concerning post-2005 labeling changes.

The few courts that have previously addressed the issue have determined that a limiting instruction to the jury is the most appropriate way to address potential prejudice. *Id.* at *3 n.2 ("Either party may, however, request a limiting instruction that neither the FDA's approval of the label, nor the fact that it required changes, is controlling on the issue of the label's adequacy."); *see also Sabel v. Mead Johnson & Co.*, 737 F. Supp. 135, 144 (D. Mass. 1990) ("Because the jury will be instructed that the FDA's opinion is not dispositive on the adequacy of the warning, defendant will have its chance to argue that its label was appropriate given its knowledge of the association of [the drug with the adverse event as of the date of prescription]."). The Court finds the evidence of post-2005 labeling of Levaquin to be admissible and not unfairly prejudicial.

III. PRE-EMPTION

Finally, defendants argue that the FDA has complete authority to institute a black box warning, and controls the content of class labeling to which Levaquin is subject, therefore any argument that defendants are liable under state law for not instituting a stronger label is pre-empted by federal law. In the Court's Order Denying the Motion to Exclude the Expert Testimony of J. Paul Waymack (08-MDL-1943, Docket No. 2263), the Court determined that the central premise of *Wyeth v. Levine* – that the manufacturer of a drug "bears responsibility for the content of its label at all times [and] is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market" – applies in this case as it is similarly premised on a drug manufacturer's duty to warn its consumers. 129 S. Ct. 1187, 1197–98 (2009).

Wyeth specifically preserved state law failure to warn claims which are the precise claims in this case. *Id.* Defendants could have altered their label through the Changes Being Effected process while maintaining the remainder of the class label, or sent out letters to prescribers ("Dear Doctor Letters"), or requested the FDA institute a black box warning earlier. Accordingly, the Court finds, as in *Wyeth*, that pre-emption does not apply to this evidence even though the subsequent labeling decision by the FDA was to include a black box warning which defendants could not have unilaterally instituted.

In sum, the Court finds that evidence of post-2005 labeling is not barred as a subsequent remedial measure, not unfairly prejudicial, not pre-empted and, as a result, admissible. The Court will consider a limiting instruction to the jury as agreed by counsel. The motion to exclude is denied.

ORDER

Based on the foregoing, and the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that Defendants' Motion in Limine to Exclude Evidence Regarding Post-2005 Levaquin Labeling [Docket No. 64] is **DENIED.**

DATED: November 24, 2010
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge